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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,801	12/19/2005	Jean-Francois Manen	27067/2012	7066
29932 7590 11/28/2007 PAULA EVANS/ C/O SONNENSCHN NATH & ROSENTHAL LLP P.O. BOX 061080 WACKER DRIVE STATION, SEARS TOWER CHICAGO, IL 60606-1080			EXAMINER SCHUBERG, LAURA J	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 11/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,801

Applicant(s)

MANEN ET AL.

Examiner

Laura Schuberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15,16,21-32,50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15,16,21-32,50 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 15, 16, 21-32, 50, 51 are pending and have been examined on the merits.

Response to Arguments

Applicant's arguments with respect to claims 15, 16, 21-32, 50 and 51 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working

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examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

Claim 16 is drawn to the method of claim 15 and further includes wherein said enzymes of said mixture are produced recombinantly. Because claim 15 does not provide specific enzymes contained in the mixture and Applicant has not provided the sequence for these enzymes, the recombinant production of the enzyme mixture would not be able to be carried out without undue experimentation. The amount of guidance provided by Applicant is deemed insufficient considering claim 15 includes an undisclosed number and type of enzymes that would require recombinant production as cited by claim 16, thus rendering the end unpredictable for all possible recombinant enzyme mixtures.

Accordingly, claim 16 fails to satisfy the enablement requirement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the physical step of isolating DNA from the treated plant tissue as suggested by the preamble of the claim. The claimed method currently only requires that the plant tissue and the enzyme mixture be combined and incubated.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15, 21-23, 50-51 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kvasenkov (RU 2061003-translation).

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Claim 15 is drawn to a method for isolating DNA from plant tissue comprising: combining plant tissue with a mixture of cell wall degrading enzymes isolated from a TW-1 mutant strain of *Trichoderma longibrachiatum* and incubating said plant tissue and said mixture of enzymes; wherein the tissue sample is from a plant selected from a group.

Dependent claims include the types of enzymes and the activity of the enzymes.

Kvasenkov teaches a method of combining the enzymes of *Trichoderma longibrachiatum* Rifai species with plant tissue from a red-colored plant (page 3 of translation) such as common beet roots (*Beta vulgaris*) and red cabbage (*Brassica oleracea*) (page 5 of translation). While the reference is silent to the exact enzymes present and their exact activity, the enzymes and their properties as claimed are deemed to be inherently present since they originate from *Trichoderma longibrachiatum*.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' enzyme mixture differs, and if so to what extent, from the enzyme mixture discussed in Kvasenkov. Accordingly, it has been established that the prior art enzyme mixture, (which originates from the same genus and species classification and shares the property of being able to degrade plant cell walls), demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed enzyme mixture that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of an enzyme mixture is not disclosed in a reference does not make the known enzyme mixture and the method of using it patentable. Clear evidence that the enzyme mixture of the cited prior art do not possess a critical characteristic that is possessed by the claimed enzyme mixture, would advance prosecution and might permit allowance of claims to Applicants' method of using an enzyme mixture for isolating DNA from plant tissue.

However, even if the reference enzyme mixture and the claimed enzyme mixture are not one and the same and there is, in fact, no anticipation, the reference enzyme mixture would, nevertheless, have rendered to one of ordinary skill in the art at the time the invention was made the claimed enzyme mixture an obvious choice based on the fact that Kvasenkov had indicated that *Trichoderma longibrachiatum* was a suitable source for the enzyme mixture. Therefore, it would have been obvious to use any and all known strains of *Trichoderma longibrachiatum* in the method of Kvasenkov.

Thus, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15, 21-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogstad et al (Plant Molecular Biology Reporter 2001).

Claim 24 includes wherein the incubation is performed in the presence of a digestion buffer comprising a DNA preserving agent.

Claim 25 includes wherein the DNA preserving agent is EDTA.

Claim 26 further includes at least one of a non-ionic detergent and PEG.

Claim 27 includes wherein the detergent is Triton-X-100.

Claim 28 includes wherein the buffer has a pH of 5.0.

Claim 29 includes wherein the incubation is performed at 50 degrees C.

Claim 30 includes agitating the mixture at 250 rpm for 1-16 hours.

Claim 31 includes adding a DNA-binding support and binding said DNA to said support after incubation.

Claim 32 includes wherein the method is automated.

Rogstad et al teach a method of DNA extraction from plants using pectinase. Suitable plant species include *Lonicera* (page 356 last paragraph). EDTA is added (page 354, step 7) and taught to be beneficial in that it preserves DNA (page 356 lines 3-7). Incubation is taught to be 6-12 hours (page 354 step 8). Related or other enzymes are taught to be suitable for addition to attain purer DNA as well as the automation of the method (page 358 Discussion).

While, Rogstad et al do not specifically teach the additional DNA extraction techniques (detergent, PEG, adding a DNA-binding support), these techniques are well known in the art of DNA extraction and would have been obvious to one of ordinary skill

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in the art for the purpose of improving the yield of DNA. The agitation speed, pH or incubation temperature would have been result effective variables and subject to routine optimization and experimentation as they would also effect the final DNA yield. The addition of other cell wall degrading enzymes would have been obvious because Rogstad et al teach that other suitable enzymes may be added.

Therefore, the teaching of Rogstad et al renders obvious Applicant's invention as claimed.

Conclusion

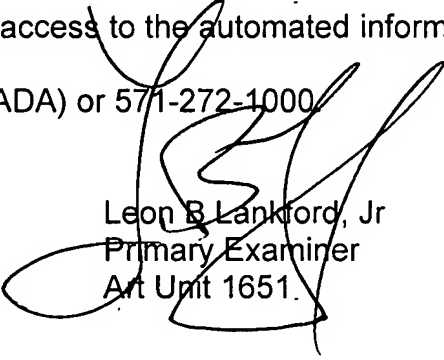
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is 571-272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leon B. Lankford, Jr
Primary Examiner
Art Unit 1651

Laura Schuberg